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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,959	08/04/2003	Takashi Nakano	239461US0CONT	4469
22850	7590	08/20/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			SHIAO, REI TSANG	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 08/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/632,959

Applicant(s)

NAKANO ET AL.

Examiner

Robert Shiao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 07/01, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 21-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/11/03, 08/04/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application claims benefit of the foreign application:
JAPAN JP2001-027367 with a filing date 02/02/2001.
2. Claims 1-31 are pending in the application.

Responses to Election/Restriction

3. Applicant's election with traverse of Group I claims 1-20, in part, in Paper No. 0704, dated July 1, 2004, is acknowledged. The traversal is on the grounds that (1) restriction of Groups I-III is improper; (2) the Office failed to meet the burden necessary in order to sustain the Restriction Requirement, and MPEP 803.02 and 821.04 are cited. This is not found persuasive and reasons are given, *infra*.

Status of the Claims

4. Claims 1-31 are pending in the application. The scope of the invention of the elected subject matter is as follows:

Claims 1-20, in part, drawn to compounds/pharmaceutical compositions of the compound of formula (I), wherein the variables Ar¹ and Ar² independently do not represent a heterocycle-containing group thereof; the variables R¹, R², R³, and R⁴ are as defined in claim 1; the variables X, Y, T, V, m, and n are as defined in claim 1.

The above mentioned withdrawn compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and

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composition from the compounds of the elected invention. The withdrawn compounds contain varying functional groups (i.e., heterocycle-containing group) which differ from those of the elected invention such as piperazine, morpholine, pyridazine, pyrimidine, etc, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e., class 544 subclass 358(+) (piperazine), class 544 subclass 106(+) (morpholine), class 544 subclass 224 (+) (pyridazine), class 544 subclass 242 (+) (pyrimidine), etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly.

The Markush group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually.

The inventions are independent and distinct because there is no patentable co-action between the groups and a reference anticipating one member will not render another obvious. Each group is directed to art recognized divergent subject matter which requires different searching strategies for each group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

The invention claims 1-20, in part, embraced in above elected subject matter are prosecuted in the case. Claims 1-20, in part, not embraced in above elected subject matter, and claims 21-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made **FINAL**.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 20 recites the limitation "in any form selected from the group consisting of dimethyl ester, diethyl ester, and diisopropyl ester", fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention, i.e., see claim 7, lines 2-3. It is unclear which variables of formula (I) comprise an ester moiety. Is it the variable Ar^1 , Ar^2 , $-X-R^2$, or $-Y-R^3$? Clarification is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

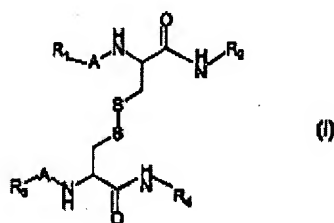
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7. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grams et al. WO 00/273378.

Applicants claims a cystine derivative of formula (I) as agents treating inflammatory disease. The compounds are found in the pages 4-7 of the specification.

Determination of the scope and content of the prior art (MPEP §2141.01)

Grams et al. disclose a cystine derivative of formula (I) for treating inflammatory disease,



, wherein the variables R_1 and R_3

independently represent linear or branched alkyl which can be substituted by an aromatic carbocyclic ring (i.e., phenyl); the variable R_2 and R_4 independently represent hydrogen or alkyl; the variable A represents a valency bond. Grams et al. compounds are agents for treating inflammatory disease, see pages 16-17. A number of compounds have been specifically exemplified, see pages 13-14.

Determination of the difference between the prior art and the claims (MPEP §2141.02)

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The difference between instant cystine derivative compounds and Grams et al. is that the variable X or Y of the instant compounds independently represents O, or NH, while Grams et al. represents NH at the same position.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the instant claims prima facie obvious **because** one would be motivated to employ the compounds of Grams et al. to obtain instant compounds/compositions of the formula of claim 1, wherein the variable Ar¹ or Ar² represents aryl group; the variables m and n independently is 1, and T₂ and V₂ independently represents hydrogen; the variable X and Y independently represent NH; R² and R³ independently represents hydrogen or alkyl; the variable R⁴ represent hydrogen or alkyl.

The motivation to make the claimed compounds derives from the expectation that the instant claimed compounds derived from known Grams et al. compounds and would possess similar activity (i.e., treating inflammatory disease) to that which is claimed in the reference.

Objection


8. Claims 1-20 are objected to as containing non-elected subject matter, i.e., heterocycle-containing group. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the elected subject matter of pages 2-3, *supra*.


Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


for Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626


Robert Shiao, Ph.D.
Patent Examiner
Art Unit 1626

8/16/04.

August 13, 2004